REMARKS

The Examiner rejected claims 25, 26, 28-34, and 36-40, while objecting to claims 27 and 35. Claims 25-40 have been cancelled herein without prejudice. Claims 55-83 have been added.

Applicant's specification fully supports new claims 55-83. For example, Figure 2 discloses a polypeptide having a human IgE CH3 domain located between two non-placental mammalian IgE domains. Thus, no new matter has been added.

New claims 55-83 have been added to follow Practice Specialist Brian Stanton's suggestions. Briefly, Practice Specialist Brian Stanton suggested presenting new sets of claims starting with subject matter such as that recited in claim 55. He also suggested presenting several dependent claims of varying scope to allow the Examiner to focus independently on each claim. Applicant notes that the claim changes made to this application were not made for reasons related to patentability, but rather were made to assist the Examiners in their examination of Applicant's inventions. Thus, the presently presented claims are entitled to their full scope, including equivalents, as provided under current U.S. patent law.

In light of the newly presented claims and the following remarks, Applicant respectfully requests reconsideration and allowance of claims 55-83.

Information Disclosure Statement

Applicants respectfully note that initialed copies of the PTO-1449 forms filed June 19, 2002, October 24, 2003, and March 26, 2004 have not been returned. Thus, Applicants respectfully request return of the initialed copies of these PTO-1449 forms. For the Examiner's convenience, copies of the PTO-1449 forms filed June 19, 2002, October 24, 2003, and March 26, 2004 are attached hereto. In addition, copies of the listed references can be resubmitted upon request.

Interview summary

Applicant and Applicant's agents thank Examiner Phuong Huynh, Supervisory Examiner Christina Chan, and Practice Specialist Brian Stanton for the courtesy of the interview on June

16, 2004. The interview included a discussion of the rejections under 35 U.S.C. § 112 within the outstanding Office Action, as well as a discussion of possible claim amendments. While no agreement was definitively reached, we thank the Examiners and Practice Specialist for their suggestions.

Objections

The Examiner objected to claim 37 because of a misspelling. Claim 37 has been cancelled. Thus, this objection is moot.

The Examiner also objected to claims 27 and 35 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Applicant acknowledges the allowability of rewritten forms of claims 27 and 35; however, claims 27 and 35 have been cancelled herein. Thus, this objection is moot.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 25, 26, 28-34, and 36-40 under 35 U.S.C. § 112, first paragraph, as lacking enablement for the reasons of record. The Examiner also rejected claims 25, 26, 28-34, and 36-40 under 35 U.S.C. § 112, first paragraph, as lacking written description for the reasons of record.

Applicant respectfully disagrees with these rejections. Applicant's specification fully enables and adequately describes the subject matter recited in previous claims 25, 26, 28-34, and 36-40. Claims 25, 26, 28-34, and 36-40 have been cancelled herein. Thus, these rejections are moot.

As suggested during the June 16, 2004 interview, new claims 55-83 are being presented to assist the Examiners in their examination of Applicant's inventions. Claim 55 recites an immunogenic polypeptide comprising a human IgE CH3 domain located between two non-placental mammalian IgE domains, while claim 72 recites an immunogenic polypeptide comprising at least an N-terminal half of a human IgE CH3 domain located between two non-placental mammalian IgE domains. Claim 82 recites an immunogenic polypeptide comprising a

means for providing a human IgE CH3 polypeptide to a human connected to a non-placental mammalian means for inducing an anti-human IgE response in said human. Applicant notes that 35 U.S.C. § 112, sixth paragraph allows claims to recite elements in a means-plus-function format. Claim 83 recites an immunogenic polypeptide consisting of a human IgE CH3 domain, an opossum IgE CH2 domain, and an opossum IgE CH4 domain.

Applicant's specification fully enables and adequately describes the subject matter recited in each of these newly presented claims. For example, a person having ordinary skill in the art at the time Applicant filed would have been able to follow the teachings provided throughout Applicant's specification to make and use an immunogenic polypeptide containing a human CH3 domain located between two non-placental mammalian IgE domains. Likewise, a person having ordinary skill in the art would have appreciated from Applicant's specification that Applicant invented the recited immunogenic polypeptides. Applicant's specification not only discloses the sequence for a human IgE CH3 domain but also discloses IgE sequences for several non-placental mammals. *See*, Figure 2 of Applicant's specification. Moreover, Applicant's specification provides the sequence for an immunogenic polypeptide containing a human CH3 domain located between two non-placental mammalian IgE domains. *See*, Figure 2 of Applicant's specification. As demonstrated from Dr. Hellman's declaration, a person having ordinary skill in the art would have been able to use common molecular biology techniques to obtain IgE sequences from non-placental mammals. Thus, taken together, it is clear that Applicant's specification fully enables and adequately describes the presently claimed invention.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejected claims 25-26, 28-34, and 36-40 under 35 U.S.C. § 103(a) as being unpatentable over Nissim *et al.* (*EMBO J.*, 10:101-107, 1991) in view of WO95/26356, Aveskogh *et al.* (*Eur. J. Immunol.*, 28:2738-50, 1998), and Hellman *et al.* (in New Horizons in Allergy Immunotherapy, Plenum Press, New York, pp. 337-342, 1996). Specifically, the Examiner stated:

> it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the non-self IgE domains from placental

mammal as taught by Nissim et al for the IgE CH2 and CH4 domains from the most evolutionary distantly related non-placental mammals such as opossum as taught by Aveskogh et al for an immunogenic polypeptide comprising a self IgE CH3 located between a non-self IgE CH2 and CH4 domains from non-placental mammal such as opossum to enhance the immunogenicity of self IgE as taught by the WO9526356 publication, Nissum [sic], Aveskogh et al and Hellman et al. Alternatively, it would have been obvious to substitute the IgE CH3 domain of opossum as taught by Aveskogh et al for the human IgE CH3 domain as taught by Hellman et al or the mouse IgE CH3 domain as taught by Nissum [sic] et al to overcome the problem of weak immunogenicity of almost all self-antigen such as IgE CH4 peptide as taught by the WO 9526356 publication for an immunogenic polypeptide comprising a self IgE CH3 domain or at least the N terminal half of a self IgE CH3 domain located between a non-self IgE CH2 and CH4 domains from non-placental mammal such as opossum to enhance the immunogenicity of self IgE as taught by the WO 9526356 publication, Nissum [sic], Aveskogh et al and Hellman et al.

Applicant respectfully disagrees. The combination of cited references does not render previous claims 25-26, 28-34, and 36-40 obvious. Claims 25-26, 28-34, and 36-40; however, have been cancelled herein without prejudice. Thus, this rejection is moot.

The combination of cited references does not render new claims 55-83 obvious. When determining obviousness, the fact that a reference teaches away from the claimed invention is a significant factor that must be considered. In fact, a "prima facie case of obviousness can be rebutted if the applicant . . . can show that the art in any material respect taught away from the claimed invention." *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant." *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353 1360 (Fed. Cir. 1999).

The Examiner stated that a person having ordinary skill in the art would have been motivated to substitute self-IgE domains with IgE domains from non-placental mammals because the WO 95/26356 publication states that an IgE CH4 decapeptide exhibits weak immunogenicity, a problem inherently associated with almost all self-antigens. Neither this reference nor the other cited references provide such a motivation. In fact, the WO 95/26356 publication discloses linking the weakly immunogenic CH4 decapeptide to a synthetic immune

stimulatory element (e.g., a *Yersinia* invasin protein) in a specific orientation to produce a potent antibody response. *See*, page 15, lines 23-28. Thus, assuming for the sake of argument that a person having ordinary skill in the art would have been motivated to increase the immunogenicity of a self polypeptide as the Examiner appears to contend, the WO 95/26356 publication teaches away from combining a human IgE CH3 domain with two non-placental mammalian IgE domains. This is because the WO 95/26356 publication reports a successful result in overcoming the "problem" of weak immunogenicity. A person having ordinary skill in the art would therefore have been led to employ the "solution" set out in the WO 95/26356 publication, and not the approach recited in the present claims. Likewise, the Hellman *et al.* reference teaches away from the presently claimed invention. If a person having ordinary skill in the art would have been motivated to increase the immunogenicity of a self polypeptide as the Examiner appears to contend, then that person upon reading the Hellman *et al.* reference would have been led in a direction that involves the use of polypeptides from parasites or bacteria such as glutathione-S-transferase (GST) or maltose binding protein (MBP) since rats injected with rat CH2-CH3 domains fused to GST or MBP produced a strong anti-IgE response.

The teaching away disclosed in these cited references not only rebuts the Examiner's *prima facie* case of obviousness but also demonstrates the non-obviousness of the presently claimed invention. As explained above, "a reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant." *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353 1360 (Fed. Cir. 1999). The WO 95/26356 publication and the Hellman *et al.* reference are such references. And, a "prima facie case of obviousness can be rebutted if the applicant . . . can show that the art in any material respect taught away from the claimed invention." *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997). Thus, the Examiner's rejection under 35 U.S.C. § 103 is improper.

In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 25-26, 28-34, and 36-40 under 35 U.S.C. § 103(a).

Provisional obviousness-type double patenting rejection

The Examiner provisionally rejected claims 25-40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-34, 36, 37, 41-43, 45-49, 51, and 53 of copending Application Number 10/176,664. Claims 27 and 35 appear to have been inadvertently included in this provisional rejection since the Examiner indicated that claims 27 and 35 would be allowable if rewritten in independent to incorporate all the limitations of the base claim. If Applicant's assumption is incorrect, clarification is respectfully requested.

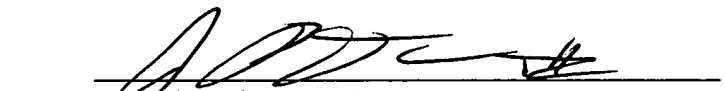
Claims 25-40 have been cancelled herein without prejudice. Thus, this provisional rejection is moot.

CONCLUSION

Applicant respectfully requests allowance of claims 55-83. The Examiner is invited to contact the undersigned agent if such would further prosecution. Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: July 12, 2004



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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 10223-006001	Application No. 09/401,636
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Lars Hellman	
		Filing Date September 22, 1999	Group Art Unit 1644

U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,483,793	11/20/84	Vyas			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	AB	0 752 886 B1	01/28/98	EPO				
	AC	WO 91/01146	02/07/91	PCT				
	AD	WO 91/11456	08/08/91	PCT				
	AE	WO 94/05698	03/17/94	PCT				
	AF	WO 94/08601	04/28/94	PCT				
	AG	WO 95/26365	10/05/95	PCT				
	AH	WO 96/12740	05/02/96	PCT				
	AI	WO 97/22699	06/26/97	PCT				
	AJ	WO 98/05684	02/12/98	PCT				
	AK	WO 99/67293	12/29/99	PCT				
	AL	WO 00/20027	04/13/00	PCT				
	AM	WO 00/32227	06/08/00	PCT				
	AN	WO 00/65058	11/02/00	PCT				
	AO	WO 02/09751	02/07/02	PCT				
	AP	WO 02/20038	03/14/02	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AQ	Basu et al., "Purification and characterization of human recombinant IgE-Fc fragments that bind to the human high affinity IgE receptor," J. Biol. Chem., 1993, 268(18):13118-13127
	AR	Nissum et al., "Fine Specificity of the IgE Interaction with the Low and High Affinity Fc Receptor," J. Immunol., 1993, 150(4):1365-1374
	AS	
	AT	

Examiner Signature	Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA						

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	AB	2,320,960	2/10/99	Canada				
	AC	2,117,193	4/1/93	Canada				

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AD	

Examiner Signature	Date Considered

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	AB						

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	AC	0 821 003	08/20/03	EPO				
	AD	1 009 382	06/18/03	EPO				
	AE							
	AF							
	AG							

Other Documents (include Author, Title, Date, and Place of Publication)

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	AI	
	AJ	
	AK	

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